510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 30 2010

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

a. Company Name:	USGI Medical
b. Company Address:	1140 Calle Cordillera San Clemente, CA 92673
c. Telephone: Fax:	(949) 369-3890 (949) 369-3891
d. Contact Person:	Mary Lou Mooney Vice President of Clinical, Regulatory & Quality
e. Date Summary Prepared:	December 29, 2010

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	g-Cinch™ Suture Grasper
b. Common Name:	Endoscopic Tissue Approximation Device
c. Classification Name:	Endoscope and accessories, 876.1500

3. IDENTIFICATION OF PREDICATE DEVICES

g-Cath Tissue Anchor Delivery Catheter	USGI Medical (K061276)
Endosuture System Endo-Holder Knot Pusher	Ethicon (K963329)

4. DESCRIPTION OF THE DEVICE

The g-Cinch Suture Grasper is a sterile, single patient use device used as an accessory to the g-Cath Tissue Anchor Delivery Catheter for grasping and cinching g-Cath Tissue Anchors. It is comprised of a proximal polycarbonate/ABS handle, flexible shaft made of medical grade polymers and a distal metal snare. It has a nominal working length of 159 cm and can be introduced through either an endoscopic access device or endoscope with a $\geq$ 2.8 mm nominal channel diameter and working length of $\leq$ 110 cm.

5. STATEMENT OF INTENDED USE

The g-Cinch is intended for use with the g-Cath Tissue Anchor Delivery Catheter for suture grasping and cinching of g-Cath Tissue Anchors.

6. COMPARISON WITH PREDICATE DEVICES

The g-Cinch Suture Grasper is comparable to the g-Cath predicate device in terms of mechanism of action, technology, and materials. Both are comprised of a proximal handle and flexible body made of medical grade polymers. Both the g-Cinch Suture Grasper and the g-Cath predicate device use a distal metal snare to engage the g-Cath suture tail and apply force to advance the g-Cath cinch to approximate the g-Cath anchor pair to create a soft tissue approximation.

7. SUMMARY OF PERFORMANCE DATA

Non-clinical performance testing was conducted to ensure that the device performs as intended when used according to its instructions for use and to demonstrate equivalence to the predicate device. Testing assessed device integrity (i.e., bond joint strength), performance, biocompatibility (in accordance with ISO 10993-1) and user ergonomics. Test data showed that the device performs as intended when used according to its instructions for use. Test data also showed that the g-Cinch met the same acceptance criteria as the g-Cath predicate device, and thereby demonstrated equivalent safety and performance to the predicate device.

In conclusion, non-clinical performance data demonstrate that the g-Cinch device is as safe, as effective and performs as well as the g-Cath predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

USGI Medical
% Ms. Mary Lou Mooney
Vice President of Clinical,
Regulatory and Quality
1140 Calle Cordillera
San Clemente, California 92673

DEC 30 2010

Re: K102931
Trade/Device Name: g-Cinch Suture Grasper
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCW
Dated: December 14, 2010
Received: December 15, 2010

Dear Ms. Mooney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 30 2010

510(k) Number (if known):

Device Name: g-Cinch Suture Grasper

Indications For Use:

The g-Cinch is intended for use with the g-Cath Tissue Anchor Delivery Catheter for suture grasping and cinching of g-Cath Tissue Anchors

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krome for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102931